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DP 1642 3/12/01



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PATENT TRADEMARK OFFICE

**In re United States Patent Application of:**

**Applicant:** Gallo et al.

**Serial No.:** 09/677,152

**Date Filed:** October 2, 2000

**Title:** THERAPEUTIC FRACTIONS OF  
SOURCES OF hCG

**Docket No.:** 4115-116 DIV 4

**Examiner:** Not yet assigned.

**Group Art Unit:** Not yet assigned.

**Paper No.:** 3

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**FIRST CLASS MAIL CERTIFICATE**

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to the Commissioner for Patents, Washington, DC 20231, and First Class Mailed under the provisions of 37 CFR 1.8.

*Lee Ann Brown*  
\_\_\_\_\_  
Lee Ann Brown

\_\_\_\_\_  
January 5, 2001  
Date of Mailing

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) numbered IE to IQ on the attached PTO-1449.

**Documents AA to IQ were previously submitted in the parent application (U.S. Patent Application No. 09/220,415); copies of such documents were previously submitted in such application.**

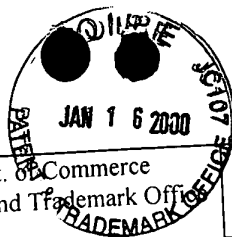
It is respectfully requested that the information listed on the attached PTO-1449 be expressly considered during the prosecution of this application, and that the reference(s) be made of record and appear among the "References Cited" on any patent to issue therefrom.



Respectfully submitted,

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4115-116 DIV4

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## INFORMATION DISCLOSURE STATEMENT

(use several sheets if necessary)

APPLICANT

Gallo et al.

FILING DATE

October 2, 2000

GROUP

1642

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## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | PATENT<br>NUMBER | ISSUE DATE | NAME | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|---------------------|------------------|------------|------|-------|----------|-------------------------------|
|                     |                  |            |      |       |          |                               |

## FOREIGN PATENT DOCUMENTS

|    | DOCUMENT<br>NUMBER | PUBLICATION<br>DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION<br>YES | NO |
|----|--------------------|---------------------|---------|-------|----------|--------------------|----|
| IE | WO 86/04241        | 31 Jul 1986         | PCT     | —     | —        |                    |    |
| IF | WO 91/16921        | 14 Nov 1991         | PCT     | —     | —        |                    |    |

## OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)

|    |   |
|----|---|
| IG | Cole, L.A. "The heterogeneity of human gonadotropin (hCG). III. The occurrence and biological and immunological activities of nicked hCG," Endocrinology, 1991 Sep, 129 (3):1559-1567   |
| IH | Cole, L.A. et al., "The biological and clinical significance of nicks in human chorionic gonadotropin and its free beta-subunit," Yale J Biol Med 1991 Nov-Dec; 64 (6):627-37   |
| II | Cole, Laurence A. "hCG, Its Free Subunits and Its Metabolites -- Roles in Pregnancy and Trophoblastic Disease," Journal of Reproductive Medicine, 1998 Jan, 43 (1): 3-10  |
| IJ | Creighton, 1993, <u>Proteins, Structures and Molecular Principles</u> (W.H. Freeman & Co., New York) pp.34-49   |
| IK | Dirnhofer, S. et al., "Functional and immunological relevance of the COOH-terminal extension of human chorionic gonadotropin beta: implications for the WHO birth control vaccine," FASEB J 1993 Nov; 7(14):1381-1385   |
| IL | Ho, H.H. et al., "Characterization of human chorionic gonadotropin peptide variants with a radio-receptor assay using recombinant human luteinizing hormone/chorionic gonadotropin receptors," Early Pregnancy 1997 Sep, 3 (3):204-12   |
| IM | Iyer, K.S. et al., "Search for peptide immunogens of the beta-subunit of human chorionic gonadotropin (hCG) capable of eliciting hormone specific and neutralizing antisera. Identification of an undecapeptide eliciting hCG-specific antisera," Int J Pept Protein Res 1992 Feb: 39(2):137-44 |
| IN | James, John S. "New Approaches to HIV Treatment: Interview with Robert Gallo, M.D.," Aids Treatment News, Dec 19, 1997, Issue 285, pp.1-7 (www.immunet.org)   |
| IO | Kardana, A. et al., "Human chorionic gonadotropin beta-subunit nicking enzymes in pregnancy and cancer patient serum," J Clin Endocrinol Metab, 1994 Sep, 79 (3):761-7  |
| IP | "Chorionic Gonadotropin," U.S. Pharmacopia (USP23)  |
| IQ | Kobata, Akira et al., "Structure, pathology and function of the N-linked sugar chains of human chorionic gonadotropin," Biochemica et Biophysica Acta 1455 (1999) 315-326   |

Continue on Page \_\_\_\_\_

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.